(Billing Code: 4150-31)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Edward J. Fox, Ph.D. (Respondent), Acting Assistant Professor in the Department of Pathology, University of Washington (UW). Dr. Fox engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grants R01 CA193649, R01 CA160674, P01 CA77852, and R01 CA102029. The administrative actions, including supervision for a period of one (1) year, were implemented beginning on March 18, 2019, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Wanda K. Jones, Dr.P.H., Interim Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Edward J. Fox, Ph.D., University of Washington: Based on Respondent's admission, an inquiry conducted by UW, and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Edward J. Fox, Acting Assistant Professor in the Department of Pathology, UW, engaged in research misconduct in research supported by NCI, NIH, grants R01 CA193649, R01 CA160674, P01 CA77852, and R01 CA102029.

Respondent neither admits nor denies ORI's finding of research misconduct related to grant application R01 CA193649-01A1. Respondent and ORI desire to close this matter without further expense of time and other resources and thus have entered into a Voluntary Settlement Agreement (Agreement). With respect to grant application R01 CA193649-01A1, Respondent acknowledges that his research records were poorly maintained and lacked the documentation necessary to support the reported preliminary results.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly:

- fabricating data and analyses in a manuscript submitted to *Nature,*[1] which was subsequently voluntarily withdrawn. These fabricated data and analyses also appear in Figure 1 of grant progress report R01 CA193649-02.[2] Respondent stated during the inquiry that two abstracts that appear in *Cancer Research*[3] are based on the fabricated data and analyses.

[1]Fox, E.J., Schmitt, M.W., Reid-Bayliss, K.S., Geraghty, R., O'Donoghue, D.P., Mulcahy, H.E., Leahy, D.T., Sheahan, K., Beckman, R.A., & Loeb, L.A. "Extensive subclonal mutations in human colorectal cancers detected by duplex sequencing." Accepted for publication in *Nature* (hereafter referred to as the "*Nature* manuscript").

[2]The subsequent grant progress report noted these data might not be reliable and indicated that the experiments were being re-run.

[3]Fox, E.J.P., Schmitt, M.W., Reid-Bayliss, K.S., Beckman, R.A., & Loeb, L.A. "Extensive subclonal mutations in human colorectal cancers detected by duplex sequencing." [Abstract]. In: Proceedings of the 107th Annual Meeting of

- fabricating or falsifying data and analyses in the preliminary results section of grant application R01 CA193649-01A1, section C.1.a(iv).

Specifically, ORI found that in the *Nature* manuscript and, where noted below, in grant progress report R01 CA193649-02 submitted to NCI, NIH, Respondent intentionally, knowingly, or recklessly:

- fabricated data for Figures 1c and 1d to show that the frequency of unique subclonal mutations in normal cells increases as people age, while the frequency of subclonal mutations in cancerous cells does not
- fabricated Figure 2b to show a pattern of subclonal mutations for the fabricated data from Figures 1c and 1d and fabricated the statistical analysis results to show statistically significant differences between tumor and normal mucosa; this figure also appears as Figure 1 in R01 CA193649-02
- fabricated data for Figure 3b to show predominantly neutral subclonal evolution
- fabricated the Extended Data Figures 1-5 and Extended Data Tables 3-5 by using the fabricated data from Figure 3b

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the American Association for Cancer Research, 2016 Apr 16-20, New Orleans, LA. Philadelphia (PA): AACR; *Cancer Res*. 76(14 Suppl):Abstract nr LB-338, 2016.

Fox, E.J.P., Schmitt, M.W., Reid-Bayliss, K.S., Beckman, R.A., & Loeb, L.A. "Extensive subclonal mutations in human colorectal cancers detected by Duplex Sequencing." [Abstract]. In: Proceedings of the AACR Special Conference on Colorectal Cancer: From Initiation to Outcomes, 2016 Sep 17-20, Tampa, FL. Philadelphia (PA): AACR; *Cancer Res*. 77(3 Suppl):Abstract nr A08, 2017.

- presented methods and data-based explanations that are fabricated because they were based on the fabricated data

ORI also specifically found that in grant application R01 CA193649-01A1, Respondent intentionally, knowingly, or recklessly:

- fabricated or falsified data for Figures 7, 8, and 9 to show how duplex sequencing methodology can document the distribution of subclonal mutations that are present in colorectal cancer
- presented data-based explanations that are fabricated or falsified because some of them were based on the fabricated or falsified data

Dr. Fox entered into an Agreement and voluntarily agreed:

(1) to have his research supervised for a period of one (1) year beginning on March 18, 2019; Respondent agreed that prior to submission of an application for U.S. Public Health Service (PHS) support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that for a period of one (1) year beginning on March 18, 2019, any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is

involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract;

(3) that if no supervisory plan is provided to ORI, Respondent will provide certification to ORI at the conclusion of the supervision period that he has not engaged in, applied for, or had his name included on any application, proposal, or other request for PHS funds without prior notification to ORI;

(4) to exclude himself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of one (1) year beginning on March 18, 2019; and

(5) as a condition of the Agreement, Respondent will recommend to the American Association for Cancer Research that the following two *Cancer Research* abstracts should be retracted:

- *Cancer Res*. 76(14 Suppl.):Abstract nr LB-338, 2016
- *Cancer Res*. 77(3 Suppl.):Abstract nr A08, 2017

Respondent will copy ORI and UW on this correspondence.

Wanda K. Jones,

Interim Director,

Office of Research Integrity.

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